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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,040	09/26/2003	Joseph Hubertus Olijve	OLIJVEDIV	7204

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,040	OLIJVE ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-49* is/are pending in the application.

4a) Of the above claim(s) *24,26,41 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,25,27-40,42 and 44-49* is/are rejected.

7)☒ Claim(s) *23,27,28-33,38-40,44-47 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/602,459.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

.DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II claims 23,25,27-40,42,44-49 in the reply filed on 06/05/2006 is acknowledged.

Claim Objections

Claims 23,27,28-33,38-40,44-47 and 49 are objected to because of the following informalities: the phrase "collagen-like" includes collagen not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claims unascertainable. Appropriate correction is required.

Claim 39 is also objected to because of the following informalities: the range of "0,005-8 mP" has a typo; the examiner believes the range should read "0.005-8 mP" and will interpret this claim as such. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 31 the statement "wherein recombinant collagen-like peptide is homodisperse" is confusing and an incomplete sentence, for instance what is the collagen dispersed in, the claim should be rewritten so that it is clear and free of grammatical errors. Regarding claim 32 the ratio of recombinant-collagen like peptide to the non-collagen peptide is said to be in a ratio but instead is listed as a weight percent. In order to expedite the examining process the examiner will read claim 31 to mean the recombinant collagen-like peptide is

homodispersed within the emulsion and the recombinant collagen-like peptide comprises 20-99% of the total peptide weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23,25,30-31,33,38,40,42 and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber (US 5,801,045).

Weber teaches emulsions that can be used as drug delivery devices comprised of collagen-like polypeptides comprised of at least 5 repeating units of Gly-X-Y where X and Y are amino acids (including proline within the weight % range cited by applicants), the peptides are within the weight range specified by applicant. See abstr, col 2 lin 54-67, col 4 lin 25-32, col 6 lin 49-58, col 15 lin 55-60, col 17 lin 31-34 and col 18 lin 42-45. Regarding claims 33 and 45 it is inherent that any polymer capable of forming a micelle type emulsion in aqueous solution would have a polar region at one end of the polymer and a non-polar region at the other, therefore because the Weber patent teaches emulsions comprised of collagen like peptides they would have an amphiphilic structure when dispersed in aqueous solution. Regarding claim 38 the concentration of the collagen-like proteins in the emulsion is met because the Weber patent teaches emulsions comprising .1% biopolymer (corresponds to 10g/1l solvent) within the range cited by applicant. See example 3. Regarding claim 40 it is inherent to those skilled in

the art that collagen does not become gelatin at room temperature until hydrolyzed, therefore the limitation in this claim is met not only by Weber but almost any collagen the examiner can envision, the burden is shifted to the applicants to show that the collagen-like peptides disclosed in Weber would exhibit gelation at temperatures lower than 30°C. Regarding claims 44 and 47 the structures I,II and III all have formulas in which the GXY triplets comprise at least 20% of the amino acids and they do not have hydroxyproline within their formulas therefore they can be considered free of hydroxyproline.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23,25,27-40,42 and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber (US 5,801,045) in view of Connelly et al. (US Patent No. 5,998,120) and in further view of Cappello et al. (US 5,496,712).

Weber is disclosed above. Regarding claim 27 it is obvious that since the collagen-like peptide disclosed in Weber has the same key structural elements as applicants claimed collagen-like peptide they would have similar if not the same properties therefore the collagen-like peptide in Weber would also be free of a helix-structure, besides this it is known to all skilled in the art that by simple hydrolysis of any collagen it becomes gelatin which is composed of random coils. Regarding claim 32, while the Weber patent is silent on the amount of recombinant collagen-like peptide compared to the whole peptide the patent does disclose that the synthetic biopolymers can be prepared by recombinant DNA technology or synthetic methods and can be used as isolated peptide sequences or be included as polypeptide sequences of biomolecules, therefore it is within the scope of the patent that the biopolymers disclosed can be connected to non-recombinant peptides. See abstr and col 5 lin 48-56. The percent of recombinant collagen to non-collagen was given no patentable weight because generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon

what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Regarding claim 35 since the Weber patent and applicants application both comprise recombinant collagen-like peptides with a polar and apolar head it is obvious that the average energy transfer of the amino acids at either end would be the same, the burden is shifted to applicant to show that the average transfer of free energy would not be the same.

The Connelly patent is used to primarily show that it was well known in the art at the time of the invention that modifying the isoelectric points of gelatin and the pH of solution were known to have an effect of the viscosity of solution and micelle size. Connelly disclosed a dispersion including a mixture of gelatins having isoelectric points lower or the same as 5.2 and 6 or higher the pH of the entire solution was 5.7 within the applicants specified ranges in claims 28 and 29. Connelly also disclosed several viscosity ranges for the two different gelatins at a pH of 5.7 and concentration by weight of 10% at a temperature of 45°C, which are within the range of applicants specified viscosities in claim 39, while the weight concentration is not the same it is obvious that since it is close and the viscosity of applicants invention and the Connelly patent are broad, they would probably overlap if the emulsions in Connelly used the same concentration of 6.6 %, burden is shifted to applicant to show that they would not have the same viscosity. Connelly also disclosed the size of the micelles formed was smaller than .5 microns, the abstract is silent on the temperature so the examiner assumes it would be at RT which would be less than 40°C, pH appeared to be 5.7 again, not quite

the same as 5 but it is obvious that since it is close and the sphere size of applicants invention and the Connelly patent are broad in that they are only less than 500 nm, they would probably overlap if the pH of the emulsions in Connelly were 5.

The Cappello patent is used to primarily show it was well known in the art that collagen-like peptides contained ends that were at least 10% of the peptide backbone each.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Weber discloses all that is claimed in applicants claimed invention but is silent on the length of the peptide ends and experimental measurements such as isoelectric points of the collagen, pH ranges of the emulsion in comparison to collagen, size of micelles as a function of pH and viscosity of the emulsion over various concentration ranges and temperature. The Connelly patent is used to primarily show that measuring and optimizing the above experimental measurements such as viscosity and micelle size was common practice in the art at the time of the invention. The Cappello patent was used to show it was well known in the art to vary the length of collagen-like peptide ends. The motivation to combine the above documents would be emulsions comprised of collagen-like recombinant polypeptides comprised of at least 5 repeating units of Gly-X-Y, the ends comprising 10% of the backbone each, the polymer having specific isoelectric points in relation to the pH of solution in order to control viscosity and droplet size. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23,30-31,33,38 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 19-20 of U.S. Patent No. 6,645,712 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim the exact same type of recombinant collagen-like peptide with all of the limitations claimed in applicant's current application being the same as '712.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER